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Kelly L. McDow-Dunham 43,787
Name of Attorney/Agent Registration No.
Signature of Attorney or Agent

612-445
P#6

P&G Case 1448.009US1 (P130)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of :
Davenport et al. : Confirmation No. 6242
Serial No. 10/087,402 : Group Art Unit 1645
Filed March 1, 2002 : Examiner

For Compositions & Methods For Increasing Amino Acid Absorption In Mammals

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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, record is being made below in a Form PTO/SB08 of documents which the Patent Office may wish to consider in connection with examination of the above-identified patent application. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case. As provided in §1.97(g), no representation is made or intended that a thorough art search was made. As provided in 37 C.F.R. §1.97(h), this Information Disclosure Statement does not constitute an admission of any kind, and specifically is not an admission that the documents listed on attached form PTO/SB08 are, or are considered to be, material to the patentability of the above-identified patent application, as defined in 37 C.F.R. §1.56(b).

1. ☐ 37 C.F.R. §1.97 (b)(1) - U.S. Direct (within 3-months of filing a regular application or converted provisional)

This information disclosure statement, submitted under 37 C.F.R. §1.97 (b)(1), is being filed within three months of the filing date of a national application. Therefore, no fee is believed to be due.

2. ☐ 37 C.F.R. §1.97 (b)(2) - Via PCT (within 3 mo. of Nat'l Stage Entry)

This information disclosure statement, submitted under 37 C.F.R. §1.97 (b)(2), is being filed within three months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application. Therefore, no fee is believed to be due.

3. ☒ 37 C.F.R. §1.97 (b)(3) - (>3 mo. after filing direct or nat'l stage entry, but before 1st O.A.)

This information disclosure statement is being submitted under 37 C.F.R. §1.97 (b)(3). Applicants have not received an Office Action on the merits in the present application. Therefore, no fee is believed to be due. However, in the event that this paper is crossing in the mail with a first Office Action on the merits, authorization is hereby given to charge the required fee pursuant to 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate of this letter is enclosed to facilitate charging of the fee, if necessary.

THE FOLLOWING IS ADDITIONAL INFORMATION PERTAINING TO (2) OR (3) MARKED WITH AN (X) ABOVE.

(a) ☐ The Notification of Acceptance of this Application Under 35 U.S.C. §371 indicates that both a copy of the International Search Report and copies of the references cited therein are present in the national stage file. In accordance with MPEP §1893.03(g), it is respectfully requested that the Examiner note the consideration of these references in the first Office Action via the PTO-892 form.

(b) ☐ The Notification of Acceptance of this Application Under 35 U.S.C. §371 indicates that a copy of the International Search Report is present in the national stage file. Copies of the references cited in that report are enclosed.

(c) ☐ The Notification of Acceptance of this Application Under 35 U.S.C. §371 does not indicate that a copy of the International Search Report and copies of the references cited are present in the national stage file. Copies of the International Search Report and references are attached.

4. ☐ 37 C.F.R. §1.97 (b)(4) - (before the mailing of a first Office Action after the filing of a request for continued examination under §1.114)

This information disclosure statement, submitted under 37 C.F.R. §1.97(b)(4), is being filed with the Request for Continued Examination (RCE) under 37 C.F.R. §1.114.

5. ☐ Information to be Considered with CPA Filing. This information disclosure statement is being filed with a Continued Prosecution Application (CPA) filed under 37 CFR 1.53(d).

6. ☐ 37 C.F.R. §1.97(c) with fee payment - (use after 1st Office Action & before Final Office Action or Notice of Allowance)

This information disclosure statement is being submitted under 37 C.F.R. §1.97(c). Applicant(s) have not received a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (e.g., *Ex parte Quayle*) as of the date of this submission. Applicant(s) elect to pay the fee set forth in 37 C.F.R. §1.17(p). Please charge the fee set forth in 37 C.F.R. §1.17(p) to Deposit Account Number 16-2480 in the name of The Procter & Gamble Company. A duplicate copy of this letter (or a fee transmittal form) is enclosed to facilitate the charging of the fee.

ADDITIONAL ITEMS TO BE NOTED BY THE EXAMINER:

☐ (1) Copies of the cited references were previously cited by or submitted to the USPTO in prior application Case No. ____, U.S. Patent Application Serial No. __, filed __. Applicants claim priority to said application under 35 U.S.C. §120. Accordingly, copies of those documents are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d).

OR

☒ (2) Copies of the cited documents are enclosed.

OR

☐ (3) Copies of all said documents, except document No.'s _____, were submitted and considered in parent application U.S. Patent Application Serial No. _____, filed _____. Applicant(s) claim priority to said application under 35 U.S.C. §120. Accordingly, copies of document No.'s _____ are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d). Copies of document No.'s _____ are enclosed. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case.

☐ (4) Pursuant to 37 C.F.R. §1.98(c), a concise explanation of the relevance of each cited reference that is not in the English language is provided.

☐ (5) Applicants also respectfully request the Examiner to consider and make of record the copending applications listed on the attached page.



Additional information is attached.

Respectfully submitted,

By

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Attorney or Agent for Applicant(s)
Registration No. 43,787
(513) 622-0159

Date: March 17, 2003

Customer No. 27752

(1448.009US1 (P130) IDS.doc

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COMPLETE IF KNOWN

| | |
|------------------------|--------------------|
| Application Number | 10/087,402 |
| Confirmation Number | 6242 |
| Filing Date | March 1, 2002 |
| First Named Inventor | Davenport et al. |
| Group Art Unit | 1645 |
| Examiner Name | |
| Attorney Docket Number | 1448.009US1 (P130) |

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|--------------------|-----------------------|--|--------------------------------|--|--|
| | | Number - Kind Code ² (if known) | | | |
| | | US-4,873,192 | 10-10-1989 | Kunkel | |
| | | US-5,231,020 | 07-27-1993 | Jorgensen et al. | |
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FOREIGN PATENT DOCUMENTS

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|-----------------------|--------------------------|--|-----------------|
| | | | |
| | | Adibi, S.A., and E. L. Morse. 1971. Intestinal transport of dipeptides in man: relative importance of hydrolysis and intact absorption. J. Clin. Invest. 50:2266-2275 | |
| | | Adibi, S.A. 1977. The oligopeptide transporter (Pept-1) in human intestine: biology and function. Gastroenterology 113:332-340 | |
| | | Brandsch, M., V. Ganapathy, and F. H. Leibach. 1995 H(+)-peptide cotransport in Madin-Darby canine kidney cells: expression and calmodulin-dependent regulation. Am. J. Physiol 268:F391-F397 | |
| | | Fei, Y.J., Y. Kanai, S. Nussberger, V. Ganapathy, F.H. Leibach, M. F. Romero, S. K. Singh, W. F. Boron, and M. A. Hediger. 1994. Expression cloning of a mammalian protoncoupled oligopeptide transporter. Nature 368:563-566 | |
| | | Ferraris, R.P., J. Diamond, and W. W. Kwan. 1988. Dietary regulation of intestinal transport of the dipeptide carnosine. Am. J. Physiol. 255:G143-G150 | |
| | | Ganapathy, V., M. Brandsch, and F. H. Leibach. 1994. Intestinal transport of amino acids and peptides. In: Physiology of the Gastrointestinal Tract, Third ed., (Johnson, L.R., ed.), pp. 1773-1794. Raven Press, New York | |
| | | Kilberg, M.S. 1989. Measurement of amino acid transport by hepatocytes in suspension and monolayer culture. Methods Enzym. 173: 564-575 | |
| | | Madin, S.H. and N.B. Darby. 1958. Established kidney cell line of normal adult bovine and ovine origin. Proc. Soc. Exp. Biol. 98:574-576. | |
| EXAMINER | | | DATE CONSIDERED |

EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| Examiner Name | |
| Attorney Docket Number | 1448.009US1 (P130) |

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|-----------------------|--------------------------|--|----------------|
| | | Matthews, J.C. 2000. Amino acid and peptide transport systems. In: Farm Animal Metabolism and Nutrition, (J.P.F.D'mello, ed.), pp. 1773-1794. CABI, New York | |
| | | Matthews, J.C., E.A. Wong, P. K. Bender, J. R. Bloomquist, and K. E. Webb, Jr. 1996. Demonstration and characterization of dipeptide transport system activity in sheep omasal epithelium by expression of mRNA in <i>Xenopus laevis</i> oocytes. J. Anim. Sci. 74:1720-1727 | |
| | | Newey, H., and D. H. Smith. 1959. The intestinal absorption of some dipeptides. J. Physiol. 145:48-56 | |
| | | Ogihara, H., T. Suzuki, Y. Nagamachi, K. Inui, and K. Takata. 1999. Peptide transporter in the rat small intestine: ultrastructural localization and the effect of starvation and administration of amino acids. Histochem. J. 31:169-174 | |
| | | Shiraga, T., K. Miyamoto, H. Tanaka, H. Yamamoto, Y. Taketani, K. Morita, I. Tamai, A. Tsuji, and E. Takeda. 1999. Cellular and molecular mechanisms of dietary regulation on rat intestinal H ⁺ /Peptide transporter PepT1. Gastroenterology 116:354-362 | |
| | | Terada, T., K. Sawada, M. Irie, H. Saito, Y. Hashimoto, and K. Inui. 2000. Structural requirements for determining the substrate affinity of peptide transporters PEPT1 and PEPT2. Pflugers. Arch. 440:679-684 | |
| | | Walker, D., D. T. Thwaites, N. L. Simmons, H. J. Gilbert, and B. H. Hirst. 1998. Substrate upregulation of the human small intestinal peptide transporter, hPepT1. J. Physiol. 507:697-706 | |
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